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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/803,580 | 03/17/2004 | Jerome C. Bressi | SYR-HDAC-5005-C2 | 6189 |
| 32793 | 7590 | 05/23/2006 | EXAMINER | |
| TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121 | | | CHANG, CELIA C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| DATE MAILED: 05/23/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/803,580 | Applicant(s) BRESSI ET AL. | |
| | Examiner Celia Chang | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/10/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-144 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-144 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-144 are pending.

2. ***Election/Restrictions***

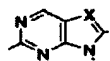
Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.


Group I, claims 109-144 and generic claims 1-108 when ZQ is 1-piperidinyl benzimidazol, drawn to bezimidazoypiperidines, classified in class 546 subclass 199+, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

Group II, claims 1-108 when ZQ is 1-piperidinepyrimidinylimidazole, i.e.

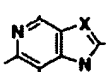
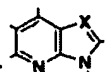


drawn to pyrimidinylimidazolyl piperidines, classified in class 544 subclass 278+, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

Group III, claims 1-108 when ZQ is 1-piperidine substituted fused bicyclic ring which

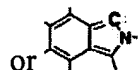
has shared nitrogen, i.e.  drawn to bicyclic ring substituted piperidines, classified in class 546 subclass 121+, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

Group IV, claims 1-108 when ZQ is 1-piperidine substituted naphthylindole/imidazole,

i.e.  or , drawn to naphthylindolyl/imidazolyl piperidines, classified in class 546, subclass 112+, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

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Group V, claims 1-108 when ZQ is piperidine substituted be indole/isoindole i.e.



drawn to compounds classified in class 546 subclass 210, depending on species election. If this group is elected a further election of a single disclosed species is also required.

Group VI, claims 1-108 when ZQ is piperidine substituted benzofuran/benzothieryl, i.e.



, Y is O/S, drawn to compounds classified in class 546 subclass 202-204, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

Group VII, claims 1-108 when ZQ is piperidine substituted non-fused five membered heterocyclic ring, classified in class 546 subclass 207+, depending on species election. If this group is elected a further election of a single disclosed species is also required.

Group VIII, claims 1-108, remaining subject matter that was not encompassed by the above groups, classified in class various, subclass various depending on species election. If this group is elected a further election of a single disclosed species is also required.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because:

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, of if there is more than one invention, inclusion is permitted if they are so slinked to form a single general inventive concept.

Annex B **Part 1(b)**, indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

Annex B **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

Annex B **Part 1(e)**, indicates that the permissible combinations of different categories of claims. **Part 1(e)I**, states that inclusion of an independent claim for a given product, an

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independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)**, indicates the “Markush practice” of alternatives in a single claim. **Part 1(f)I**, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f) iv**, indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, take alone, be considered justification for finding a lack of unity. **Part 1(f)v**, indicates that “When dealing with alternatives, if it can be shown that at least *one* Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner”

In the instant case, at least one Markush alternative is not novel because prior art by Lam et al. CA 140:12453 anticipated compounds of Group VII, thus the lacking of unity of invention has been found.

Further more, the different core structure as delineated supra as groups I-VIII indicated different utility i.e. indolylpiperidines have factor Xa inhibition activity (see Lam supra), other core structure such as benzimidazolyl piperidine hydroxamic acid of Kakuchi (WO2005/073180) have inhibiting activity in generation of AGE. Lacking of an art recognized common core is proper ground for restriction.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

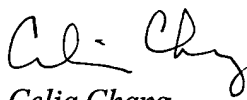
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
May 17, 2006


Celia Chang
Primary Examiner
Art Unit 1625